DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 82N-0330 and 82N-0332]

Tamper-Resistant Packaging Requirements for Certain Over-The-Counter Human Drug and Cosmetic Products and Contact Lens Solutions and Tablets; Availability of Advisory Opinion and Information on Packaging Technologies

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an advisory opinion, issued in response to a citizen petition, that stays until February 6, 1984, that provision of the tamper-resistant packaging regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product. This advisory opinion applies to over-the-counter drugs, cosmetic products, and contact lens solutions and related products subject to the tamper-resistant packaging regulations. In addition, the agency announces that as part of its Tamper-Resistant Packaging Compliance Program, it plans to maintain a current list of acceptable technologies and those packaging technologies that the agency believes are unacceptable or have problems. Elsewhere in this issue of the Federal Register, the agency is amending the tamper-resistant packaging regulations with regard to the stay of the effective date.

ADDRESS: Requests for single copies of th advisory opinion and the Tamper-Resistant Packaging Compliance Program to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: On the advisory opinion: Paul O. Fehnel, National Center for Drugs and Biologics (HFN-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

On the Tamper-Resistant Packaging Compliance Program: William C. Drury, National Center for Drugs and Biologics (HFN-330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3790.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 5, 1982 (47 FR 50442), FDA published regulations establishing tamper-resistant packaging and labeling requirements for certain over-the-counter (OTC) human drugs and cosmetic products. In the same issue of the Federal Register (47 FR 50452), the agency also published tamper-resistant regulations for contact lens solutions and tablets. In the Federal Register of April 19, 1983 (48 FR 16658), the agency amended its tamper-resistant packaging and labeling regulations for OTC drug and cosmetic products to clarify certain sections of the preamble and to specify in the regulations those products that the agency had exempted from these regulations. In the same of the Federal Register (48 FR 16665), the agency made similar clarifying amendments for contact lens solutions and tablets. One of the clarifying labeling amendment added by the April 19, 1983 rule was the statement "If the tamper-resistant feature chosen to meet the requirement in paragraph (b) of this section is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement."

A. Advisory Opinion Concerning "Identifying Characteristics"

On May 5, 1983, the agency received a petition from the Proprietary Association requesting a stay of the effective date of a portion of the tamper-resistant packaging and labeling regulations. Specifically, the association sought a stay of that provision of the regulations that requires a specific label reference to any identifying characteristic that is incorporated into the tamper-resistant feature of a particular product. For OTC drugs, this statement is required by 21 CFR 211.132(c), as amended by the April 19, 1983 publication. Cosmetic products and contact lens solutions and tablets are subject to the same labeling provision by 21 CFR 700.25(c) and 800.12(c), respectively, as amended April 19, 1983.

The agency agreed with the petitioner that additional time to comply with the requirement that any identifying characteristic of the tamper-resistant feature be specifically referred to in the labeling should be provided and stayed the effective date for this requirement until February 6, 1984. Thus, the requirement for a specific label reference to any identifying characteristic would apply to each affected product packaged on or after

February 6, 1984. Because such a stay affects not only OTC human drugs, but also cosmetic products and contact lens solutions and tablets, the Commissioner of Food and Drugs made the petition response an advisory opinion. Therefore, this response may be relied on by manufacturers and packers of all affected products. A copy of this advisory opinion is on file at the Dockets Management Branch. Elsewhere in this issue of the Federal Register, the agency is amending the tamper-resistant packaging regulations with regard to the stay of the effective date.

B. Availability of Information on Tamper-Resistant Packaging Technologies

In the preamble to the tamper-resistant packaging and labeling regulations published in the Federal Register of November 5, 1982 (47 FR 50444), the agency listed 11 technologies which at that time it considered suitable to meet the intent of the regulations. The agency also stated that the technologies listed were merely intended to be examples, and that the list was not intended to preclude technological innovation that might result in totally different but equally acceptable systems for providing protection to the consumer.

In response to the final tamper-resistant rule, several comments requested that a "new" method of packaging be included in the FDA list of acceptable technologies. In the April 19, 1983 clarifying amendments, the agency discussed these comments but declined to revise the list because the list was not intended to be inclusive. The agency emphasized again that the list of technologies was never intended to be complete, that the agency did not intend that technological innovation be precluded, and that manufacturers and packagers are free to adopt any packaging system, whether or not listed in the preamble to the final rule, if it meets the definition of tamper-resistant packaging provided in the regulations. Further, the agency indicated that the use of a technology listed in the preamble does not, by itself, constitute compliance with the requirement for the use of a tamper-resistant packaging system, because the performance characteristics of some technologies vary widely.

Although the agency has concluded that the list of 11 technologies in the preamble should not be revised, it does recognize that there is a need to make available a document that contains the current agency thinking on acceptable tamper-resistant technologies as well as those technologies for which the agency has identified a problem. It is important that such information be communicated to FDA investigators as well as to the affected industry. The agency has concluded, therefore, that the most appropriate procedure for communicating this information is to make it a part of the "Tamper-Resistant Packaging Compliance Program," No. 7356.838, originally issued on June 1, 1983. The agency will supplement this compliance program as necessary. Setting forth this information in the compliance program will both disseminate this information to FDA field investigators and, because compliance programs are available under the agency's freedom of information regulations (21 CFR Part 20), provide a mechanism whereby the information will be available to other interested persons. A copy of the Tamper-Resistant Compliance Program and the current supplements will be available for review in the Dockets Management Branch under the docket numbers found in brackets in the heading of this document. Requests for single copies of the Tamper-Resistant Compliance Program or the supplement concerning packaging technologies should be sent to the Dockets Management Branch.

Dated: August 11, 1983.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

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